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#15/Brief

On August 13, 2003

TOWNSEND and TOWNSEND and CREW LLP

By: Digi Hoover

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE
BOARD OF PATENT APPEALS AND INTERFERENCES**

In re application of:

MILLER, ROSS

Application No.: 09/751,577

Filed: December 29, 2000

For: METHODS AND SYSTEMS FOR
TREATING TEETH

Examiner: JOHN J. WILSON

Art Unit: 3732

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**APPELLANT'S BRIEF
UNDER 37 C.F.R. § 1.192**

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Alexandria, VA 22313-1450

Sir:

Appellant offers this Appeal Brief in furtherance of the Notice of Appeal filed on January 13, 2003 in the above-referenced patent application. This Appeal Brief is submitted in triplicate as required by 37 C.F.R. § 1.192(a). Please deduct the requisite fee, pursuant to 37 C.F.R. § 1.17(c), of \$320 from deposit account 20-1430, and deduct any additional fees or credit any excess fees associated with the Appeal Brief to such deposit account. Appendix A, attached hereto, contains a copy of all claims pending in this case.

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REAL PARTY IN INTEREST:

All right, title, and interest in the subject invention and application are assigned to Align Technology, Inc., having offices at 881 Martin Avenue, Santa Clara, California 95050. Therefore, Align Technology, Inc. is the real party interest.

RELATED APPEALS AND INTERFERENCES

No other appeals or interferences are known which will directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

STATUS OF THE CLAIMS

Claims 1-38 were originally presented in the application. Claims 1-38 have been rejected. Claims 1-38 are the subject of this appeal. No other claims are pending.

STATUS OF AMENDMENTS

A Final Office Action was mailed on August 20, 2002. An amendment under 37 C.F.R. § 1.116 was filed in response to this Final Office Action on January 13, 2003. An Advisory Action was mailed on February 3, 2003 indicating that the after final amendment had been considered but did not place the application in condition for allowance. A copy of all the pending claims, prior to the after final amendment, is provided in Appendix A attached hereto.

An after appeal amendment under 37 C.F.R. § 1.116 is being filed concurrently herewith.

SUMMARY OF THE INVENTION

The present invention is related generally to the field of orthodontics and more particularly relates to methods and systems for moving a patient's teeth from an initial tooth arrangement to a final tooth arrangement for the straightening of teeth. Application filed December 29, 2000 (Application), page 1, lines 8-10. Repositioning is accomplished with a hybrid treatment system of a series of polymeric shell appliances (e.g., positioners) in combination with one or more conventional wire and bracket systems (e.g., braces) to effect full treatment of the teeth. *Id.*, page 4, lines 3-10.

The appealed claims are directed at a system for repositioning teeth from an initial tooth arrangement to a final tooth arrangement. Claim 1; Application, page 4, lines 2-5. The system comprises a plurality of dental incremental position adjustment appliances including a series of digitally generated appliances and one more wire and bracket systems. *Id.* The series of appliances are configured to be placed successively on the patient's teeth and to incrementally reposition the individual teeth in a series of successive steps, i.e., from one arrangement, through a plurality of intermediate tooth arrangements, and to a subsequent arrangement. Application, page 4, lines 5-8. The series of appliances, typically from three to twenty-five appliances, are configured to receive the teeth in a cavity, wherein the appliances each have a geometry selected to reposition the teeth from one arrangement to a subsequent arrangement. Claim 1; Application, page 4, lines 18-29; page 5, lines 3-6. In particular, the series of appliances generally comprise polymeric shells having cavities, wherein the cavities of successive shells have different geometries shaped to receive and resiliently reposition teeth from the one arrangement to the subsequent arrangement. Claim 1; Application, page 4, lines 18-29. One or more wire and bracket systems are also employed to progressively reposition the teeth from one arrangement to a successive arrangement. *Id.* The hybrid treatment system of braces and positioners are deployed in seriatim to reposition the patient's teeth from the initial tooth arrangement to the final tooth arrangement so as to effect a full a course of tooth movement. *Id.*

The appealed claims are also directed to methods for repositioning teeth. Claims 6, 12, 20, and 26. In one method, the positioners and braces are deployed in a preselected order to reposition teeth from an initial tooth arrangement to a final tooth arrangement. Claim 6; Application, page 4, lines 25-29. The preselected order may comprise employing a series of appliances first in order to achieve certain treatment goals prior to finishing or further treatment with a wire and bracket system. Application, page 4, lines 31-33; Fig. 8. Conversely, the preselected order may comprise employing a wire and bracket system first in order to partially reposition the teeth to bring the patient within certain guidelines regarding the appropriate use of the series of appliances. *Id.*, page 4, lines 29-31. The hybrid treatment method of placing three or more appliances successively in combination with one or more wire and bracket systems is

performed in a preselected order to reposition the patient's teeth from the initial tooth arrangement to the final tooth arrangement. Claim 6; Application, page 6, lines 4-10.

An improved method for repositioning teeth using appliances comprises polymeric shells having cavities shaped to receive and resiliently reposition teeth to produce a final tooth arrangement. Claim 12; Application, page 6, lines 16-23. The improvement comprises determining at the outset of treatment geometries for at least three appliances to be used in combination with at least one wire and bracket system. *Id.* The appliances are to be worn successively by a patient to reposition the teeth from an initial tooth arrangement to the final tooth arrangement, wherein the cavities of successive shells have different geometries. *Id.* Hence, this improved method employs a hybrid treatment plan at the outset of treatment.

Methods for treating a dental malocclusion are further being appealed. One method comprises providing criteria to distinguish between a less severe malocclusion and a more severe malocclusion. Claim 26; Application, page 7, line 31-33. Exemplary criteria includes A-P correction of greater than 2 mm, autorotation of the mandible required for vertical/A-P correction, CR-CO discrepancy correction/treatment to other than centric occlusion, correction of moderate to severe rotations of premolars and/or canines that are greater than 20 degrees, severe deep bite opened to ideal or open bite to be closed to ideal extrusion of teeth greater than 1 mm other than as part of torquing or in conjunction with intruding adjacent teeth, teeth tipped by more than 45 degrees, multiple missing teeth, crowns less than 70% of normal size, posterior open bite, and movement of entire arch required for A-P correction. Claim 27; Application, page 5, lines 15-29. Whether an individual patient's malocclusion is more or less severe is determined in accordance with the criteria. Claim 26; Application, page 7, line 34 through page 8, line 9.

Usually, patients who are free from all of the individual criteria set forth above will be considered to have a less severe malocclusion, thereby indicating treatment with a plurality of successive polymeric shell appliances without the use of a wire and bracket system. *Id.* If, on the other hand, the malocclusion is determined to be more severe, the indicated treatment plan will include both the use of the polymeric shell appliances as well as the use of a wire and bracket system. *Id.* These hybrid treatment method steps are employed in a

predetermined order. *Id.* For instance, the predetermined order may be to treat the patient's teeth first with the braces and follow up with appliances. Claim 34; Application, page 8, lines 6-8. Conversely, the predetermined order may be to treat the patient's teeth first with the appliances and then with braces. Claim 35; Application, page 8, lines 6-8. In either course, the combined treatment will be sufficient to reposition the teeth to a final desired arrangement to effect full treatment of the teeth. Claim 26; Application, page 8, lines 8-9.

ISSUES

I. Whether claims 1-5 are unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 4,591,341 issued to Andrews in view of U.S. Patent No. 3,950,851 issued to Bergersen, U.S. Patent No. 4,348,178 issued to Kurz, and U.S. Patent No. 5,454,717 issued to Andreiko et al.

II. Whether claims 12-31 and 33-38 are unpatentable under 35 U.S.C. § 103(a) over Andrews in view of Bergersen and Kurz.

III. Whether claims 6-11 are unpatentable under 35 U.S.C. § 103(a) over Andrews in view of Kurz.

IV. Whether claims 1-32 are unpatentable under 35 U.S.C. § 103(a) over Andrews in view of U.S. Patent No. 5,975,893 issued to Chishti et al.

GROUPING OF THE CLAIMS

Appellant submits that the claims do not stand or fall together. As Appellant will argue more fully below, claims 1, 6, 12, 20, 26, 34, and 35 each independently define elements patentable over the cited art. Hence, only independent claims 1 and 20 and dependent claims 2-5 and 21-25 stand together; independent claims 6 and 26 and dependent claims 7-11, 27-33, and 36-38 stand together; independent claim 12 and dependent claims 13-19 stand together; dependent claim 34 stands by itself; and dependent claim 35 stands by itself.

ARGUMENT

I. Whether claims 1-5 are unpatentable under 35 U.S.C. § 103(a) over Andrews in view of Bergersen, Kurz, and Andreiko et al.

In the Final Office Action dated August 20, 2002, claims 1-5 were rejected under Section 103(a) as allegedly being unpatentable over Andrews in view of Bergersen, Kurz, and Andreiko et al. Appellant respectfully traverses this rejection for the following reasons discussed below.

The present rejection does not establish *prima facie* obviousness under 35 U.S.C. § 103 and M.P.E.P. §§ 2142-2143. The Examiner bears the initial burden to establish and support *prima facie* obviousness. *In re Rinehart*, 189 U.S.P.Q. 143 (CCPA 1976). To establish *prima facie* obviousness, three basic criteria must be met. M.P.E.P. § 2142. First, the Examiner must show some suggestion or motivation, either in the prior art references or in the knowledge generally available to one of ordinary skill in the art, to combine the reference teachings so as to produce the claimed invention. M.P.E.P. § 2143.01; *In re Fine*, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). Secondly, the Examiner must establish that there is a reasonable expectation of success for the modifications. M.P.E.P. § 2142. Thirdly, the Examiner must establish that the prior art references, alone or in combination, teach or suggest all the claim limitations. M.P.E.P. § 2143.03; *In re Royka*3, 180 U.S.P.Q. 580 (CCPA 1974). Appellant respectfully submits that a *prima facie* case of obviousness has not been met because the Examiner's rejection fails on at least two of the above requirements.

Firstly, Appellant notes that no motivation or suggestion, either in the cited art references or in the knowledge generally available to one of ordinary skill in the art, has been cited the Examiner to combine the reference teachings so as to produce the claimed invention. Independent claim 1 reads as follows:

A system for repositioning teeth from an initial tooth arrangement to a final tooth arrangement, said system comprising a plurality of dental incremental position adjustment appliances including:

a plurality of digitally generated appliances, each having a geometry selected to reposition the teeth from a first arrangement to a second arrangement, wherein the appliances comprise polymeric shells having cavities and wherein the cavities of successive shells have different geometries shaped to receive and resiliently reposition teeth from the first to the second arrangement; and

one or more wire and bracket systems to progressively reposition the teeth from one arrangement to a successive arrangement, the wire and bracket systems and appliances

being deployed in seriatim to reposition teeth from the initial tooth arrangement to the final tooth arrangement.

This hybrid treatment system of a plurality of digitally generated successive polymeric shell appliances in combination with one or more wire and bracket systems has not been suggested by the cited art references. The Examiner asserts that Andrews teaches that it is known to use a bracket and wire system followed in series by a mouthpiece, albeit not a mouthpiece made from a polymeric shell. Final Office Action dated August 20, 2002, page 2. To cure this deficiency, the Examiner relies on Bergersen for teaching that it is known to form a mouthpiece as a polymer shell. *Id.* The Examiner further asserts that Kurz teaches using successive shells including intermediate appliances. *Id.* The Examiner also asserts that Andrieko et al. teaches digitally forming appliances. *Id.*, page 3. Appellant respectfully disagrees.

While the Examiner relies on Andrews for teaching use of a "mouthpiece" after conventional wire and bracket orthodontic treatment, it is disclosed that this mouthpiece is simply a single tooth positioner for finishing the teeth after the wire and bracket system. Col. 1, lines 13-27. The Examiner further relies on Bergersen to teach the use of a polymeric shell appliance in place of the mouthpiece of Andrews. Such reliance is not understood. Bergersen in fact teaches a generally conventional positioner which is really not much different than the mouthpiece described in Andrews. Col. 1, lines 11-17.

In any event, Andrews, either alone or in combination with Bergersen, at best teaches using a single finisher (possibly in the form of a polymeric shell) to achieve final tooth positioning after conventional wire and bracket tooth treatment. However, Andrews either alone or in combination with Bergersen, still fails to disclose or remotely provide a suggestion or motivation for the use of a plurality of successive appliances, as even the Examiner concedes. Final Office Action dated August 20, 2002, page 2. The Examiner attempts to remedy this deficiency by combining the teachings of Andrews and Bergersen with the disclosure of Kurz. In particular, the Examiner states, "[i]t would be further obvious to one of ordinary skill in the art to modify the above combination to include using successive appliances as shown by Kurz in

order to make use of known methods of moving teeth in series to obtain the desired results." *Id.* Such reliance is misplaced.

Appellant has reviewed the Kurz reference in detail and finds that not only is the desired motivation for the combination absent, but that this reference consistently and expressly teaches against the combination being made by the Examiner. Kurz discloses a vibrational orthodontic appliance, namely vibrating mouth piece positioners 16 powered by a motor 10. Col. 2, lines 33-36; Fig. 1. In particular, in col. 1, lines 59-68, Kurz discloses that "[b]ecause of the reduced need for patient cooperation, the appliance of the invention can be used to treat a malocclusion through a series of positioners from the **initial malocclusion to the finished correction without other orthodontic appliances [e.g., braces].**" (Emphasis added). Further, Kurz again notes in col. 3, lines 22-39,

[b]y the use of the appliance of the present invention, malocclusions, no matter how pronounced can be corrected by a series of vibrating mouth piece positioners....so that the teeth may be moved from their **initial position....toward the ideal occlusion....**In this way, vibrational positioners may in a step-by-step manner carry the occlusion towards the ideal positions **without the use of any other orthodontic appliances.**

(Emphasis added).

Appellant notes that hindsight reconstruction is impermissible. As the Examiner is certainly aware, the suggestions or motivations for the proposed combination must be found in the prior art or in the knowledge of one of skill in the art, rather than in Appellant's disclosure.

In re Vaeck, 20 U.S.P.Q.2d 1438 (CAFC 1991). The Examiner continues to argue that

Kurz uses conditional language, 'can be' or 'may' when describing the use of the invention without any other orthodontic appliances. This does not negate the teaching of Kurz that a solution to the problem of moving teeth can be solved with the use of plural shells. Kurz does not teach that the invention cannot be use with other appliances. Further, applicant's invention, may or may not be used with other appliance, and therefore, no criticality can be attributed to this feature.

The present invention of claim 1 clearly requires successive use of both pluralities of polymeric shell appliances and wire and bracket tooth repositioning systems. Kurz nowhere describes or suggest that the vibrational positioners may be used with other orthodontic appliances as the Examiner argues. In fact, Kurz unequivocally states "without other orthodontic appliances" which clearly contraindicates the combination of Kurz with Andrews and/or Bergersen. Kurz specifically teaches against using multiple appliance system described therein with any other orthodontic appliances. As such, one of ordinary skill in the art would have been generally discouraged to replace the post-braces single mouthpiece of Andrews with the vibrational positioners of Kurz as Kurz provides a stand alone treatment for moving teeth from an initial malocclusion to the finished correction. A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303 (Fed. Cir. 1983).

Secondly, even assuming that the cited art disclosures may be combined (which combination is disputed), the cited art references still fail to teach or suggest all of the limitations of claim 1. In particular, the combination of references asserted by the Examiner nowhere teaches or suggests the digital generation of successive polymeric shell appliances, as required by claim 1. The Examiner however asserts that "Andreiko has been applied to show using computers to digitally generate appliances." Final Office Action dated August 20, 2002, page 7. Andreiko et al. does not show the claimed digitally generated appliances, each having a geometry selected to reposition the teeth from a first arrangement to a second arrangement, wherein the appliances comprise polymeric shells having cavities that move teeth. Andreiko's "appliances" correspond to conventional braces (i.e., archwires, brackets, and jigs). See Fig. 1. Hence, at best, the inclusion of Andreiko et al. suggest the digital design of wires and bracket systems.

Under *Vaeck*, absent any evidence of a cited suggestion or reasonable motivation in the cited art references, or knowledge of those skilled in the art, for providing a hybrid treatment system of a plurality of digitally generated successive polymeric shell appliances in conjunction with one or more wire and bracket systems to effect a full course of tooth movement, *prima facie* obviousness of independent claim 1 (and dependent claims 2-5) has not

been established. As such, it is respectfully requested that the § 103(a) rejection of claim 1 (and dependent claims 2-5) be withdrawn and the claims be allowed.

II. Whether claims 12-31 and 33-38 are unpatentable under 35 U.S.C. § 103(a) over Andrews in view of Bergersen and Kurz.

In the Final Office Action, claims 12-31 and 33-38 were rejected under Section 103(a) as allegedly being unpatentable over Andrews in view of Bergersen and Kurz. Appellant respectfully traverses this rejection for the following reasons discussed below.

Independent claim 12 is directed to an improved method for repositioning teeth using polymeric shell appliances. In particular, the improvement comprises **determining at the outset of treatment** geometries for at least three appliances to be used in combination with at least one wire and bracket system. The appliances are to be worn successively by a patient to reposition teeth from an initial tooth arrangement to the final tooth arrangement, wherein cavities of the successive shells have different geometries. Hence, this improved method employs a hybrid treatment plan of at least three polymeric shell appliances and a wire and bracket system. As such, *prima facie* obviousness of claim 12 (and dependent claims 13-19) has not been shown for many of the reasons given above with respect to claim 1 (section I, *supra*) and accordingly the claims should be allowed.

In addition, claim 12 requires that this hybrid treatment plan be determined at the outset of treatment, i.e., the treating professional decides in the beginning that a combination treatment plan of at least three appliances are to be employed in conjunction with a wire and bracket system. This hybrid treatment plan is well thought out before hand and is typically based on a variety of criteria, such as a severe malocclusion, treating professional's judgment, patient consent, particular patient's condition and prognosis, etc. Application, page 5, lines 16 -29; page 6, line 1-3. The cited art references, alone or in combination, fail to remotely teach or suggest this additional step of determining at the outset of treatment that a hybrid treatment plan of at least three appliances and wire and brackets are to be employed. Hence, independent claim 12 (and dependent claims 13-19) are further allowable over the cited art references.

Independent claim 20 is also directed to an improved method for repositioning teeth using polymeric shell appliances. In particular, the improvement comprises repositioning

the teeth using a wire and bracket system to initially reposition the teeth prior to applying at least three polymeric shell appliances. Hence, as claim 20 includes similar limitations as those found in claim 1, it is respectfully requested that the § 103(a) rejection of independent claim 20 (and dependent claims 21-25) be withdrawn and the claims be allowed for the reasons set forth in section I, *supra*.

Independent claim 26 reads as follows:

*A method for treating a dental malocclusion, said method comprising:
providing criteria to distinguish between a less severe malocclusion and a more severe malocclusion;
determining whether an individual patient's malocclusion is more severe or less severe according to the criteria;
if the malocclusion is determined to be less severe, treating the patient with a plurality of successive polymeric shell appliances having different geometries selected to resiliently reposition teeth to a final desired arrangement; and
if the malocclusion is determined to be more severe, treating the patient successively in a **predetermined order** with (a) at least one wire and bracket system, and (b) a plurality of successive polymeric shell appliances having different geometries selected to resiliently reposition teeth, wherein the combined treatment repositions the teeth to a final desired arrangement.*

As this claim similarly is directed to treating a patient with a hybrid treatment plan in the instance of a severe malocclusion, *prima facie* obviousness of claim 26 (and dependent claims 27-38) has not been shown for many of the reasons given above with respect to claim 1 (section I, *supra*) and accordingly the claims should be allowed.

In addition, claim 26 requires that a severe malocclusion determination be made prior to prescribing a hybrid treatment plan based on a variety of criteria. See Summary of the Invention, *supra*. Further, once a severe determination is made, the patient is treated successively according to a predetermined order. For example, the predetermined order may comprise employing a plurality of appliances first in order to achieve certain treatment goals prior to finishing or further treatment with a wire and bracket system. Application, page 4, lines 31-33; Fig. 8. Conversely, the predetermined order may comprise employing a wire and bracket system first in order to partially reposition the teeth to bring the patient within certain guidelines regarding the appropriate use of the plurality of appliances. *Id.*, page 4, lines 29-31.

The Examiner states that the "method steps claiming how and when the articles are intended to be used are matters of intended use of known structures and not given patentable weight." Advisory Action dated February 3, 2003, page 2. Appellant respectfully disagrees. It is well established that every claim limitation must be taught or suggested by the cited art, alone or in combination. *In re Royka*, 180 U.S.P.Q. 580 (CCPA 1974) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."). Appendix B, attached hereto, is a copy of the American Heritage Dictionary (1985) definition of "predetermined" which shows that the ordinary and plain meaning of the term 'predetermined' is to "decide or establish in advance." Appellant submits that independent claim 26 is further allowable over the cited art because there is no description or suggestion in any of the cited art references of record to perform these additional claimed steps. In particular, the cited art references, alone or in combination, fail to remotely teach or suggest (1) requiring that a severe malocclusion determination be made prior to prescribing a hybrid treatment plan and (2) that if such a severe malocclusion determination is made, the patient be treated successively according to a predetermined¹ order. As such, independent claim 26 (and dependent claims 27-38) are further allowable over the cited art references.

In addition to relying on novel and non-obvious independent claim 26, dependent claims 34 and 35 recite specific novel and non-obvious aspects of the invention not disclosed in the cited art. For example, claim 34 further defines that the predetermined order is to treat the patient's teeth first with the wire and bracket system to partially reposition the teeth until the malocclusion is less severe according to the criteria and then treating the patient with the polymeric shell appliances. As discussed above, the cited art references of record fail to teach any predetermined treatment order, much less one that prescribes braces first (until the malocclusion is less severe) followed up with successive polymeric shell appliances. Claim 35 further defines that the predetermined order is to treat a patient's teeth first with the polymeric

¹ The element "predetermined" has been constructed by the Federal Circuit in other issued patents. For example, in an unpublished opinion, in construing the claim element "means for storing a collection of predetermined beveling or grooving paths" the Federal Circuit stated that "the plain meaning of a predetermined beveling path is a beveling path that has been set previously." *Essilor Int'l. v. Nidek Co. Ltd. et al.*, 1999 U.S.App.LEXIS 28426 (CAFC 1999). (Emphasis added).

shell appliances and then with the wire and bracket system. Andrews at best teaches a single tooth positioner for finishing the teeth **after** the wire and bracket system. Hence, claims 34 and 35 are further allowable over the cited art references.

III. Whether claims 6-11 are unpatentable under 35 U.S.C. § 103(a) over Andrews in view of Kurz.

In the Final Office Action, claims 6-11 were rejected under Section 103(a) as allegedly being unpatentable over Andrews in view of Kurz. Independent claim 6 is directed to a hybrid treatment method of placing three or more appliances successively in combination with one or more wire and bracket systems. This treatment method is performed in a **preselected order** to reposition the patient's teeth from the initial tooth arrangement to the final tooth arrangement. As such, this rejection is respectfully traversed for many of the same reasons given above with respect to claim 1 (section I, *supra*) and claim 26 (section II, *supra*) and accordingly claim 6 (and dependent claims 7-11) should be allowed.

IV. Whether claims 1-32 are unpatentable under 35 U.S.C. § 103(a) over Andrews in view of U.S. Patent No. 5,975,893 issued to Chishti et al.

In the Final Office Action, claims 1-32 were rejected under Section 103(a) as allegedly being unpatentable over Andrews in view of Chishti et al. Appellant respectfully traverses this rejection for the following reasons discussed below.

As an initial matter, Appellant notes that the Chishti et al. patent is assigned to the assignee of the present application and represents earlier work of the assignee. The Chishti et al. patent is being relied upon for teaching a series of polymeric shell appliances for incrementally moving teeth. Final Office Action dated August 20, 2002, page 6. Appellant concedes that the Chishti et al. patent teaches the series of appliances recited in each of independent claims 1, 6, 12, 20, and 26. The present invention of independent claims 1, 6, 12, 20, and 26, however, teaches a hybrid treatment solution of a plurality of polymeric shell appliances in conjunction with a one or more wire and bracket systems to provide a complete treatment.

Appellant respectfully submits that a *prima facie* case of obviousness has not been met for two reasons. First, Appellant notes that no motivation or suggestion, either in the cited art references or in the knowledge generally available to one of ordinary skill in the art, has been

cited the Examiner to combine the reference teachings so as to produce the claimed invention. Andrews fails to disclose or remotely provide a suggestion or motivation for the use of a plurality of successive polymeric shell appliances, as even the Examiner concedes. Final Office Action dated August 20, 2002, page 6. The Examiner attempts to remedy this deficiency by combining the teachings of Andrews with the disclosure of Chishti et al. In particular, the Examiner states, "[i]t would be obvious to one of ordinary skill in the art to modify Andrews to include using a plurality of successive polymeric shell as shown by Chishti in order to make use of well known mouthpiece structures for moving teeth in a desired manner." *Id.* The Examiner further states, "Chishti also teaches that the shells can replace wire and bracket does not obviate this." Advisory Action dated February 3, 2003, page 2. Appellant respectfully disagrees.

Chishti et al. teaches that the multiple polymeric shell system taught in that patent is useful as a **replacement** for wire and bracket systems. In particular, in col. 1, line 65 through col. 2, line 6, it states

use of conventional braces is a tedious and time consuming process and requires many visits to the orthodontist's office. Moreover, from the patient's perspective, the use of braces is unsightly, uncomfortable, presents a risk of infection, and makes brushing, flossing, and other dental hygiene procedures difficult. For these reasons, it would be desirable to provide alternative methods and systems for repositioning teeth.

Hence, not only is the desired motivation absent from the cited references, Chishti et al. clearly teaches against a combination treatment that includes wire and bracket systems.

Appellant notes that references can not be arbitrarily combined. There must be some reason why one skilled in the art would be motivated to make the proposed combination of references. *In re Nomiya*, 184 U.S.P.Q. 607 (CCPA 1975). Further, the Examiner bears the initial burden of factually establishing and supporting any *prima facie* conclusion of obviousness. *In re Rinehart*, 189 U.S.P.Q. 143 (CCPA 1976); M.P.E.P. § 2142. If the Examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness. *Id.* In the instant case, the Examiner has not pointed to any evidence in the cited art references, or how knowledge of those skilled in the art, provide a suggestion or

motivation to combine the reference teachings of Chishti et al. with Andrews so as to produce the hybrid treatment system of claims 1, 6, 12, 20, and 26. See *In re Zurko*, 59 U.S.P.Q.2d 1693 (Fed. Cir. 2001) ([I]n a determination of patentability the Board cannot simply reach conclusions based on its understanding or experience - or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings).

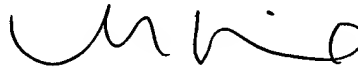
Secondly, even assuming that the cited art disclosures may be combined (which combination is disputed), this combination would fall far short of the producing the claimed invention of independent claims 1, 6, 12, 20, and 26. Appellant believes that one skilled in the art combining the teachings of Andrews and Chishti et al. would, if anything, substitute the polymeric shell appliances of Chishti et al. for the wire and bracket system relied upon in Andrews. Thus, the combination would be the use of the Chishti et al. polymeric shell appliance system with a final single mouthpiece used for achieving finishing of the tooth positions. While such a combination may or may not be obvious, it is simply not what is being claimed in the present invention. As such, it is respectfully requested that the § 103(a) rejection of claims 1-32 be withdrawn and the claims be allowed.

CONCLUSION

Appellant believes that the above discussion is fully responsive to all grounds of rejection set for the in the Final Office Action dated August 20, 2002.

If for any reasons the Examiner believes a telephone conference would in any way expedite resolution of the issues raised in this appeal, the Examiner is invited to telephone the undersigned at 415-273-8317.

Respectfully submitted,



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APPENDIX A
COMPLETE SET OF PENDING CLAIMS

1. (Previously Presented) A system for repositioning teeth from an initial tooth arrangement to a final tooth arrangement, said system comprising a plurality of dental incremental position adjustment appliances including:

a plurality of digitally generated appliances, each having a geometry selected to reposition the teeth from a first arrangement to a second arrangement, wherein the appliances comprise polymeric shells having cavities and wherein the cavities of successive shells have different geometries shaped to receive and resiliently reposition teeth from the first to the second arrangement; and

one or more wire and bracket systems to progressively reposition the teeth from one arrangement to a successive arrangement, the wire and bracket systems and appliances being deployed in seriatim to reposition teeth from the initial tooth arrangement to the final tooth arrangement.

2. (Previously Presented) A system as in claim 1, wherein the tooth positions defined one or more cavities in each successive appliance differ from those defined by the prior appliance by no more than 2 mm.

3. (Original) A system as in claim 1, comprising at least two intermediate appliances.

4. (Original) A system as in claim 3, comprising at least ten intermediate appliances.

5. (Original) A system as in claim 4, comprising at least twenty-five intermediate appliances.

6. (Original) A method for repositioning teeth from an initial tooth arrangement to a final tooth arrangement, said method comprising the following steps performed in a preselected order:

successively placing three or more appliances having geometries selected to progressively reposition the teeth from a first arrangement to successive arrangements; and

placing one or more wire and bracket systems to progressively reposition the teeth from one arrangement to a successive arrangement, the brackets and appliances being deployed in seriatim to reposition teeth from the initial tooth arrangement to the final tooth arrangement.

7. (Previously Presented) A method as in claim 6, where the tooth positions defined by one or more cavities in each successive appliance differ from those defined by the prior appliance by no more than 2 mm.

8. (Original) A method as in claim 6, wherein the successively placing step comprises placing at least two additional appliances prior to placing the final appliance.

9. (Original) A method as in claim 8, wherein the successively placing step comprises placing at least ten additional appliances.

10. (Original) A method as in claim 9, wherein the successively placing step comprises placing at least twenty-five additional appliances.

11. (Original) A method as in claim 6, wherein the appliances are successively replaced at an interval in the range from 2 days to 20 days.

12. (Original) An improved method for repositioning teeth using appliances comprising polymeric shells having cavities shaped to receive and resiliently reposition teeth to produce a final tooth arrangement, wherein the improvement comprises determining at the outset of treatment geometries for at least three appliances to be used in combination with at least one wire and bracket system, the appliances are to be worn successively by a patient to reposition

teeth from an initial tooth arrangement to the final tooth arrangement, wherein the cavities of successive shells have different geometries.

13. (Original) An improved method as in claim 12, wherein at least four geometries determined at the outset.

14. (Original) An improved method as in claim 13, wherein at least ten geometries are determined at the outset.

15. (Original) An improved method as in claim 14, wherein at least twenty-five geometries are determined at the outset.

16. (Original) An improved method as in claim 12, wherein the tooth positions defined by the cavities in each successive appliance differ from those defined by the prior appliance by no more than 2 mm.

17. (Original) A method as in claim 16, comprising at least two intermediate appliances.

18. (Original) A method as in claim 17, comprising at least ten intermediate appliances.

19. (Original) A method as in claim 18, comprising at least twenty-five intermediate appliances.

20. (Original) An improved method for repositioning teeth using appliances comprising polymeric shells having cavities shaped to receive and resiliently reposition teeth to produce a final tooth arrangement, wherein the at least three appliances are applied successively to a patient's teeth to reposition the teeth, wherein the improvement comprises repositioning the teeth using a wire and bracket system to initially reposition the teeth prior to applying the polymeric shell appliances.

21. (Original) An improved method as in claim 20, wherein at least four appliances are applied to the teeth.

22. (Original) An improved method as in claim 21, wherein at least ten appliances are applied to the teeth.

23. (Original) An improved method as in claim 22, wherein at least twenty-five appliances are applied to the teeth.

24. (Original) An improved method as in any of claims 20-23, wherein initially repositioning the teeth using a wire and bracket system configures the teeth to render them amenable to treatment with polymeric appliances.

25. (Original) An improvement as in claim 24, wherein initially repositioning the teeth alleviates at least one of the following conditions:

- A-P correction of greater than 2 mm;
- autorotation of the mandible required for vertical/A-P correction;
- CR-CO discrepancy correction/treatment to other than centric occlusion;
- correction of moderate to severe rotations of premolars and/or canines that are greater than 20 degrees;
- severe deep bite opened to ideal or open bite to be closed to ideal;
- extrusion of teeth greater than 1 mm other than as part of torquing or in conjunction with intruding adjacent teeth;
- teeth tipped by more than 45 degrees;
- multiple missing teeth;
- crowns less than 70% of normal size;
- posterior open bite; and
- movement of entire arch required for A-P correction.

26. (Original) A method for treating a dental malocclusion, said method comprising:

- providing criteria to distinguish between a less severe malocclusion and a more severe malocclusion;
- determining whether an individual patient's malocclusion is more severe or less severe according to the criteria;
- if the malocclusion is determined to be less severe, treating the patient with a plurality of successive polymeric shell appliances having different geometries selected to resiliently reposition teeth to a final desired arrangement; and
- if the malocclusion is determined to be more severe, treating the patient successively in a predetermined order with (a) at least one wire and bracket system, and (b) a plurality of successive polymeric shell appliances having different geometries selected to resiliently reposition teeth, wherein the combined treatment repositions the teeth to a final desired arrangement.

27. (Original) A method as in claim 26, wherein the criteria which are characteristic of a more severe malocclusion include at least some of the following:

- A-P correction of greater than 2 mm;
- autorotation of the mandible required for vertical/A-P correction;
- CR-CO discrepancy correction/treatment to other than centric occlusion;
- correction of moderate to severe rotations of premolars and/or canines that are greater than 20 degrees;
- severe deep bite opened to ideal or open bite to be closed to ideal;
- extrusion of teeth greater than 1 mm other than as part of torquing or in conjunction with intruding adjacent teeth;
- teeth tipped by more than 45 degrees;
- multiple missing teeth;
- crowns less than 70% of normal size;
- posterior open bite; and

movement of entire arch required for A-P correction.

28. (Original) A method as in claim 27, wherein the absence of some or all of the criteria characteristic of a severe malocclusion indicates that it is a less severe occlusion.

29. (Original) A method as in any of claims 26-28, wherein providing criteria comprises providing a list of criteria.

30. (Original) A method as in claim 26, wherein determining whether the malocclusion is more or less severe comprises obtaining a model of the patient's teeth.

31. (Original) A method as in claim 30, wherein the model is a cast.

32. (Original) A method as in claim 30, wherein the model is digital.

33. (Original) A method as in claim 26, wherein determining whether the malocclusion is more or less severe comprises visually observing the patient's teeth.

34. (Original) A method as in claim 26, wherein the predetermined order is to treat the patient's teeth first with the wire and bracket system to partially reposition the teeth until the malocclusion is less severe according to the criteria and then treating the patient with the polymeric shell appliances.

35. (Original) A method as in claim 26, wherein the predetermined order is to treat the patient's teeth first with the polymeric shell appliances and then with the wire and bracket system.

36. (Original) A method as in claim 26, wherein treating the patient with a plurality of successive polymeric shell appliances comprises successively placing at least three appliances each over a time period in the range from one to four weeks.

37. (Original) A method as in claim 36, wherein at least ten successive polymeric appliances are placed.

38. (Original) A method as in claim 36, wherein at least twenty-five successive polymeric appliances are placed.

Pendant in the form of a stylized figure